



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CASPER *et al.*

Appl. No.: 10/806,613

Filed: March 22, 2004

For: **Low Dose Estrogen Interrupted
Hormone Replacement Therapy**

Confirmation No.: 2635

Art Unit: 1617

Examiner: Badio, Barbara P.

Atty. Docket: 2710.0990003/JUK/MEK

**Revocation of Prior Power of Attorney and
Appointment of New Attorneys of Record**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned, having express authority to represent Duramed Pharmaceuticals, Inc., a co-assignee of the entire right, title, and interest in the captioned application, by assignment filed at the U.S. Patent and Trademark Office herewith (copy enclosed), with exclusive right to prosecute the captioned application, hereby revokes all powers of attorney heretofore given in the above-captioned application, and appoints as his attorneys, the attorneys associated with Customer Number 26111, with full power of substitution, association, and revocation, to prosecute said application and to transact all business in the United States Patent and Trademark Office connected therewith.

For the purpose of PAIR, the Customer Number is 26111.

The undersigned hereby grants said attorneys the power to insert on this Power of Attorney any further identification that may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

BEST AVAILABLE COPY

Send all correspondence to:

Customer Number 26111
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934.

Direct telephone calls to (202) 371-2600.

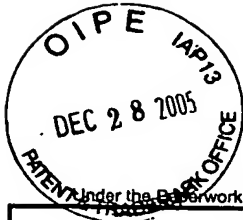
FOR: Duramed Pharmaceuticals, Inc.

SIGNATURE: 

BY: FREDERICK J. KILLION

TITLE: SECRETARY

DATE: 12/22/05



STATEMENT UNDER 37 CFR 3.73(b)

2710.0990003/JUK/MEK

Applicant/Patent Owner: Casper et al.

Application No./Patent No.: 10/806,613 Filed/Issue Date: March 22, 2004

Entitled: Low Dose Estrogen Interrupted Hormone Replacement Therapy

Duramed Pharmaceuticals, Inc., a corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
The extent (by percentage) of its ownership interest is _____ %

in the patent application/patent identified above by virtue of either:

A ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B ☒ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

Gary A. Shangold and

1. From: Militza K. Ausmanas To: Ortho-McNeil Pharmaceutical, Inc.

The document was recorded in the United States Patent and Trademark Office at
Reel 015942, Frame 0893, or for which a copy thereof is attached.

2. From: Ortho-McNeil Pharmaceutical, Inc. To: King Pharmaceuticals, Inc.

The document was recorded in the United States Patent and Trademark Office at
Reel 015942, Frame 0883, or for which a copy thereof is attached.

3. From: King Pharmaceuticals, Inc. To: Duramed Pharmaceuticals, Inc.

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☒ Additional documents in the chain of title are listed on a supplemental sheet.

☒ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

FREDERICK J. KILLON
Signature

12/22/05
Date

Printed or Typed Name

Telephone Number

SECRETARY

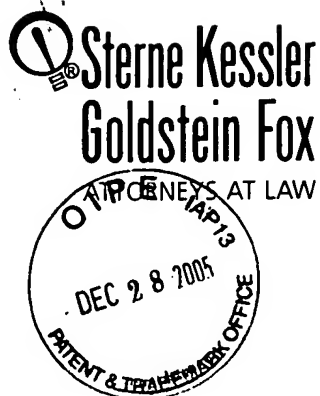
Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Statement Under 37 CFR 3.73(b) (supplemental sheet)

1. From: Robert F. Casper To: Jencap Research Ltd.
Assignment Agreement executed February 10, 1987 (*see* SKGF Cover Letter and Attachment A).
2. From: Jencap Research, Ltd. To: Ortho Pharmaceutical Corporation
Agreement executed February 25, 1988, giving Ortho Pharmaceutical Corporation exclusive license Jencap Research, Ltd. patents (*see* SKGF Cover Letter and Attachment B).
3. From: Ortho-McNeil Pharmaceutical, Inc. (Formerly Ortho Pharmaceutical Corporation) To: King Pharmaceuticals, Inc.
Agreement executed April 26, 2002 (*see* SKGF Cover Letter and Attachment C).
4. From: King Pharmaceuticals, Inc. To: Duramed Pharmaceuticals, Inc.
Agreement executed November 22, 2004 (*see* SKGF Cover Letter and Attachment D).



Robert Greene Sterne
Edward J. Kessler
Jorge A. Goldstein
David K.S. Cornwell
Robert W. Esmond
Tracy-Gene G. Durkin
Michele A. Cimballa
Michael B. Ray
Robert E. Sokohl
Eric K. Steffe
Michael Q. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcorn
Robert C. Millonig
Donald J. Featherstone
Timothy J. Shea, Jr.
Michael V. Messinger
Judith U. Kim

Patrick E. Garrett
Jeffrey T. Helvey
Heidi L. Kraus
Eldora L. Ellison
Thomas C. Fiala
Albert L. Ferro
Donald R. Banowitz
Peter A. Jackman
Jeffrey S. Weaver
Kendrick P. Patterson
Vincent L. Capuano
Brian J. Del Buono
Virgil Lee Beason
Theodore A. Wood
Elizabeth J. Haanes
Joseph S. Ostroff
Frank R. Cottingham
Rae Lynn P. Guest
Daniel A. Klein

Jason D. Eisenberg
Michael D. Specht
Andrea L. Kamage
Tracy L. Muller
Jon E. Wright
LuAnne M. DeSantis
Ann E. Summerfield
Aric W. Ledford
Helene C. Carlson
Cynthia M. Bouchez
Timothy A. Doyle
Gabry L. Longworth
Lori A. Gordon
Nicole D. Dretar
Ted J. Ebersole
Laura A. Vogel
Michael J. Mancuso
Bryan S. Wade
Aaron L. Schwartz

Shannon A. Carroll*
Wesley W. Jones*
Matthew E. Kelley*
Michelle K. Holoubek*
Marsha A. Rose*

Registered Patent Agents*
Karen R. Markowicz
Nancy J. Leith
Matthew J. Dowd
Katrina Yujian Pei Quach
Bryan L. Skelton
Robert A. Schwartzman
Teresa A. Colella
Victoria S. Rutherford
Simon J. Elliott
Julie A. Heider
Mita Mukherjee

Scott M. Woodhouse
Christopher J. Walsh
Liliana Di Nola-Baron
Peter A. Socarras
Jeffrey Mills

Of Counsel
Kenneth C. Bass III
Marvin C. Guthrie

*Admitted only in Maryland
*Admitted only in Virginia
*Practice Limited to
Federal Agencies

December 28, 2005

WRITER'S DIRECT NUMBER:
(202) 772-8638
INTERNET ADDRESS:
MKELLEY@SKGF.COM

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1617

Attn: Mail Stop Petition

Re: U.S. Utility Patent Application
Application No. 10/806,613; Filed: March 22, 2004
For: **Low Dose Estrogen Interrupted Hormone Replacement Therapy**
Inventors: CASPER *et al.*
Our Ref: 2710.0990003/JUK/MEK

Sir:

Provided herein are redacted copies of four Agreements. These Agreements demonstrate that Duramed Pharmaceuticals, Inc. is co-owner of U.S. Appl. No. 10/806,613 with an exclusive right to prosecute the application and transact all business in the U.S. Patent and Trademark Office (USPTO).

Portions of the following Agreements have been redacted to protect the confidentiality of the parties involved:

Attachment A: Agreement between Robert F. Casper ("Casper") and Jencap Research, Ltd. ("Jencap"), "The Casper/Jencap Agreement" (2 Sheets)

- Sheets 1-2 (pages 1-2 of 2 of the Casper/Jencap Agreement) identify the parties involved in the agreement, indicate that the "invention rights" were assigned to Jencap, and contain the signature of Casper, dated February 10, 1987.

Attachment B: Agreement between Jencap and Ortho Pharmaceutical Corporation ("Ortho"), "The Jencap/Ortho Agreement" (8 Sheets)

- Sheets 1-2 (pages 1-2 of 30 of the Jencap/Ortho Agreement) identify the parties involved in the agreement, indicate the date of execution of the Agreement as

May 1, 1987, and show that under the terms of the agreement Ortho obtained an exclusive license to Jencap products;

- Sheets 3-4 (pages 3-4 of 30 of the Jencap/Ortho Agreement) define the terms "product" and "patents" (relating to contraceptive or hormone replacement products);
- Sheets 5-6 (pages 10-11 of 30 of the Jencap/Ortho Agreement) indicate that Jencap retained all responsibility to file, prosecute and maintain patent applications and patents under the terms of the agreement;
- Sheets 7-8 (pages 29-30 of the Jencap/Ortho Agreement) contain signatures of representatives of Ortho and Jencap as well as a notarized signature of Robert F. Casper, and indicate the Agreement was executed February 25, 1988.

Attachment C: Purchase Agreement between Ortho-McNeil Pharmaceutical, Inc. ("OMP," formerly Ortho) and King Pharmaceuticals, Inc. ("King"), "The OMP/King Agreement" (5 Sheets)

- Sheet 1 (page 1 of 8 of the OMP/King Agreement) identifies the parties involved in the agreement to assign rights and obligations, the date of execution of the agreement as April 26, 2002, acknowledges the Casper Agreements, and identifies U.S. Provisional Appl. No. 60/126,970 and any and all continuations, C-I-P's, divisionals, reissues, reexaminations, renewals and/or extensions thereof as subject to the terms described in the OMP/King Agreement for the "Casper Patents" (U.S. Appl. No. 10/806,613 is a continuation of U.S. Appl. No. 10/134,455, which is a continuation of U.S. Appl. No. 09/538,485, which claims benefit of U.S. Appl. No. 60/126,970);
- Sheets 2-3 (two copies of page 6 of 8 of the OMP/King Agreement) contain signatures of the parties executing the Agreement;
- Sheets 3-5 (pages 6-8 of 8 of the OMP/King Agreement) identifies that Jencap and Casper agree to the terms of the Agreement and that Jencap and Casper agree to appoint counsel designated by King to prosecute all business in the USPTO with respect to the Casper patents, which includes U.S. Appl. No. 10/806,613; and
- Sheet 5 (page 8 of 8 of the OMP/King Agreement) contains the signatures of Robert F. Casper, indicates that Jencap and Casper agree to the terms of the agreement, and identifies the date of execution of the Agreement as April 26, 2002.

Attachment D: Purchase Agreement between King and Duramed Pharmaceuticals, Inc. ("Duramed") "The King/Duramed Agreement" (9 Sheets)

- Sheet 1 (page 1 of 37 of the King/Duramed Agreement) identifies the parties involved in the agreement, and identifies the date of execution of the agreement as November 22, 2004;
- Sheet 2 (page 8 of 37 of the King/Duramed Agreement) identifies that the terms of the agreement are limited to the "Product Intellectual Property" and the "Casper Rights;"
- Sheets 3-4 (pages 14-15 of 37 of the King/Duramed Agreement) define the term "Product Intellectual Property," outline terms of the agreement that relate to intellectual property, and identify patents listed in Section 1.01(ppp) of the Seller Disclosure as intellectual property transferred under the terms of the agreement;
- Sheets 5-6 (Signature pages of the King/Duramed Agreement) contain signatures of the parties executing the Agreement;
- Sheet 7 (Section 1.01(ppp) of the King/Duramed Agreement) identifies U.S. Appl. No. 10/806,613 as an asset transferred under the Agreement and indicates that U.S. Appl. No. 10/806,613 is co-owned per the rules of Section 6.11(a) and 6.11(b); and
- Sheets 8-9 (Sections 6.11(a) and 6.11(b) of the King/Duramed Agreement) identifies that Duramed co-owns U.S. Appl. No 10/806,613 with Jencap Research, Ltd. and Robert F. Casper. In particular, Section 6.11(a) indicates that the King/Duramed agreement is subject to the terms of the Assignment of Rights and Obligations, entered into April 26, 2002, by and between King, OMP, Jencap and Casper (*see* Attachment C, Sheets 3-5).

In conclusion, the documents listed above demonstrate that Duramed Pharmaceuticals, Inc. co-owns U.S. Appl. No. 10/806,613 with an exclusive right to prosecute and conduct business before the USPTO.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Matthew E. Kelley
Attorney for Applicants
Registration No. 55,887

JUK/MEK/A-L/lam
Enclosures

480109.1

RESOLUTION OF THE DIRECTORJENCAP RESEARCH LTD.

WHEREAS pursuant to an Agreement dated the 10th day of February, 1987 between the Corporation, as purchaser, and Dr. Robert Casper, as vendor, (the "Agreement") the Corporation purchased, on the terms and conditions set out in the Agreement, the invention and all rights pertaining thereto of the vendor in consideration of the payment by the Corporation to the vendor of [REDACTED] to be represented by the issue by the Corporation to the vendor of [REDACTED] common shares;

AND WHEREAS, pursuant to the Agreement, the Corporation is now required to issue the said common shares to the vendor;


NOW THEREFORE BE IT RESOLVED THAT

1. the purchase by the Corporation of the invention on the terms and subject to the conditions set out in the Agreement, a copy of which has been submitted to the director, is hereby sanctioned, ratified and confirmed;
2. the entering into by the Corporation of the said Agreement is hereby sanctioned, ratified and confirmed;
3. it is hereby determined that:
 - (a) the amount of money which the Corporation would have received if such common shares had been issued for money would have been [REDACTED] per share, being a consideration of [REDACTED] in the aggregate; and
 - (b) the said invention has a fair value of [REDACTED];
4. the Corporation having received the said invention rights in full payment of the consideration in respect of the said common shares as provided in the Agreement, the said [REDACTED] common shares are hereby issued to the vendor;
5. pursuant to subsection 24(3) of the Business Corporations Act, 1982, the Corporation shall add to the stated capital account maintained for the common shares of the Corporation [REDACTED] in the aggregate in respect of the said common shares being issued to the vendor hereby;
6. the execution by and on behalf of and in the name of the Corporation of the Agreement by Dr. Casper and under the corporate seal of the Corporation is hereby sanctioned, ratified and confirmed; and

- 2 -

7. Dr. Casper in his position as President and/or a director of the Corporation is hereby authorized and directed on behalf of and in the name of the Corporation to do all other acts and things and to sign all such other documents, either under the corporate seal of the Corporation or otherwise as may in his opinion be necessary or desirable in order to give effect to the foregoing, including without limitation the filing of any appropriate election in prescribed form pursuant to subsection 85(1) of the Income Tax Act (Canada).

Each of the foregoing resolutions are hereby consented to by the sole director of the Corporation pursuant to the Business Corporations Act, 1982 this *10th* day of *February*, 1987.


Robert F. Casper

LICENSE AGREEMENT

This Agreement, effective as of the 15th day
of MAY, 1984, by and between ROBERT F. CASPER, M.D.,
("CASPER"), an individual residing at 868 Hellmuth Avenue,
London, Ontario, Canada N6A3T8, and JENCAP RESEARCH, LTD., an
Ontario corporation with offices at the same address ("JENCAP")
and ORTHO PHARMACEUTICAL CORPORATION ("ORTHO"), a New Jersey
corporation with offices at Route 202, Raritan, New Jersey
08869.

W I T N E S S E T H:

WHEREAS, CASPER has developed improved products for
contraception and hormone replacement therapy and intends to
continue developing such products; and

WHEREAS, CASPER has the full right and title to these
improved products, including the right to grant exclusive
licenses thereto; and

WHEREAS, CASPER has assigned the full right and title to
these improved products to JENCAP; and

WHEREAS, ORTHO has proven experience in the development,
clinical trials, registration, manufacture, and marketing of
products for contraception and Hormone replacement therapy; and

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WHEREAS, ORTHO wishes to obtain from ~~JENCAP an exclusive~~
~~license to these products and JENCAP is willing to grant such a~~
~~license,~~ all as specified herein;

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants set forth below, CASPER, JENCAP and ORTHO mutually agree as follows:

ARTICLE I
DEFINITIONS

For the purposes of this License Agreement the following definitions shall apply:

1.1 Affiliate shall mean any company or entity controlled by, controlling or under common control with ORTHO, "control" for purposes of this definition meaning that forty percent (40%) or more of the voting stock or participating profit interest of the controlled company is owned or controlled, directly or indirectly, by the controlling company.

1.2 Development means reasonable efforts and activities (consistent with ORTHO's other business obligations) in the Territory necessary to evaluate and develop the Product for human health use, including but not limited to undertaking pharmacological, toxicological, pharmaceutical and clinical investigations and studies in order to obtain all necessary approvals to market the Product in the Territory.

1.3 Effective Date shall mean the date first written above.

1.4 Know-How shall mean all inventions, discoveries, trade secrets, information, experience, data, formulas, procedures and results, and improvements thereon, developed by and proprietary to JENCAP which relate to or are used directly in connection with the development, manufacture, or use of contraceptive or hormone replacement products.

1.5 Net Sales shall mean the sum total of all charges invoiced to customers by ORTHO and Affiliates for sale of Product(s), less normal trade and cash discounts actually allowed, credits or refunds actually allowed for spoiled, damaged, outdated, or returned goods, and sales or other excise taxes imposed and paid directly with respect to the sale; provided, however, that sales between ORTHO and any of its Affiliates or between any of such Affiliates shall not be included in such computation.

1.6 Patents shall mean all patent applications relating to contraceptive or hormone replacement products developed by and proprietary to JENCAP or to methods for making or using such products which are filed prior to or during the term of this Agreement in the United States or any foreign jurisdiction, including any addition, continuation, continuation-in-part, or

division thereof or any substitute application therefor; any patent issued with respect to such patent application; any reissue or extension of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent.

1.7 Product shall mean any and all contraceptive and hormone replacement products including without limitation, estrogen and progestin replacement drugs, drug administration regimens, formulations, and methods, the manufacture, sale or use of which utilizes Know-How or Patents.

1.8 Territory shall mean all countries of the world as to which ORTHO shall not have terminated the licenses granted herein.

1.9 Valid Claim shall mean a claim of an unexpired issued patent of Patents which shall not have been withdrawn, cancelled, or disclaimed nor held invalid by a court of competent jurisdiction in an unappealed or unappealable decision. The scope of a Valid Claim shall be interpreted so as to reflect the construction placed upon it in a decision by any such court holding it valid.

(b) ORTHO shall provide JENCAP, on an annual basis, with an status report of all health registration applications and approvals for the Product in the Territory.

(c) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

5.7 JENCAP agrees that, upon request by ORTHO, JENCAP shall enter into separate agreements with Affiliates in or outside Canada, granting such Affiliates rights under Know-How and Patents to manufacture, use, and sell Products. Such licenses shall contain the same terms and conditions as contained in this Agreement to the extent permitted by the laws of the jurisdiction in which each such Affiliate is located.

ARTICLE VI

FILING, PROSECUTION, AND MAINTENANCE OF PATENT RIGHTS

6.1 JENCAP shall file, prosecute, and maintain all patent applications and patents under Patents. In order to provide the broadest possible scope of protection for Patent Rights, JENCAP will allow ORTHO the opportunity to review and comment upon all proposed patent applications under Patent Rights.

Nonwithstanding this opportunity, however, the final decision on all patent filings shall be made by JENCAP. All such applications shall be filed first in Canada.

6.2 JENCAP agrees, when requested in writing by ORTHO, to file patent applications corresponding to the Canadian patent applications included in Patent Rights in countries outside Canada; provided however, JENCAP shall have the right to file and secure patents at its expense in such countries in which ORTHO elects not to seek patent protection.

[REDACTED]

IN WITNESS WHEREOF, ORTHO and JENCAP have caused this Agreement to be executed in duplicate by their duly authorized officer and CASPER has executed the agreement in duplicate.

ATTEST:

ORTHO PHARMACEUTICAL CORPORATION

Gary V. Parlin

Name: Gary V. Parlin

Title: President

Date: 2/25/88

By: Barbara L. Pyle

ATTEST:

JENCAP RESEARCH LTD.

Robert F. Casper, M.D.
President
Date: Jan 28/88

By: [Signature]

ROBERT F. CASPER, M.D.
(as an Individual)

[Signature]
Date: Jan 28/88

Province
STATE OF ONTARIO)
)SS
COUNTY OF MIDDLESEX)

DOMINION OF CANADA

BE IT REMEMBERED, that on this 28th day of January, 1988,
before me, a Notary Public, personally appeared
ROBERT F. CASPER, who I am satisfied is the person named above
and who executed the foregoing instrument in my presence, and I
first having made known to him the contents thereof, he did
acknowledge that he signed, sealed, and delivered the same as
his voluntary act and deed for the uses and purposes therein
expressed.



Notary Public

ASSIGNMENT OF RIGHTS AND OBLIGATIONS

This assignment of rights and obligations (the "Agreement") is entered into as of April __, 2002 by and between:

Ortho-McNeil Pharmaceutical, Inc., a corporation of the State of Delaware, having a principal place of business at U.S. Route 202, P.O.Box 300, Raritan, NJ 08869-0602, and successor in interest to Ortho Pharmaceutical Corporation, a corporation of the State of New Jersey, (hereinafter OMP or Seller) and

King Pharmaceuticals, Inc. a corporation of the State of Tennessee, having principal offices located at 501 Fifth Street, Bristol, Tennessee 37620, (hereinafter KING or Purchaser).

WHEREAS, OMP and KING have entered into that certain Asset Purchase Agreement dated as of April 26, 2002 ("Asset Purchase Agreement"); and

WHEREAS, in connection with such Asset Purchase Agreement, OMP wishes to assign certain rights and obligations and KING wishes to acquire all such rights and assume all such obligations as set forth below, with such assignment to be effective upon the closing of the Asset Purchase Agreement.

NOW, THEREFORE, OMP and KING, for good and valuable consideration the sufficiency of which is hereby acknowledged agree as follows:

1) Definitions:

- a) CASPER AGREEMENTS shall mean the (i) the Assignment by Robert F. Casper to Jencap Research, Ltd. ("Jencap") dated February 10, 1987, (ii) the License Agreement between Robert F. Casper, Jencap Research and Ortho Pharmaceutical Corporation dated May 1, 1987, (iii) the Agreement between Jencap, Medicor Development, Robert F. Casper and Ortho Pharmaceutical Corporation dated December 1, 1994 (to the extent it is still in effect), and (iv) the Letter of Acknowledgement by Robert F. Casper dated February 11, 1999.
- b) CASPER PATENT(S) shall mean U.S. Patent No. 5,108,995, U.S. Patent No. 5,382,573, U.S. Patent Appln. No. 09/538,485 filed March 30, 2000 and U.S. Provisional Appln. No. 60/126,970 filed March 30, 1999, and any and all continuations, continuations-in-part, divisionals, reissues, reexaminations, renewals and/or extensions thereof and any patents issued on the foregoing.
- c) EFFECTIVE DATE shall mean the date on which this Agreement becomes effective, which shall be the Closing Date under the Asset Purchase Agreement.
- d) PRODUCT shall mean the cyclophasic steroidal product for hormone replacement therapy approved for sale in the United States under NDA 021040 and bioequivalents thereto and any use, manufacture, sale or packaging thereof.
- e) TERRITORY shall mean the United States of America, its territories and possessions (including the Commonwealth of Puerto Rico).

- 15) This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement.
- 16) The article and section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.
- 17) This Agreement shall be construed, interpreted and the rights of the parties determined in accordance with the laws of the State of New Jersey without reference to the choice of law provisions thereof.
- 18) This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, OMP and KING have caused this agreement to be executed in duplicate by their duly authorized officer

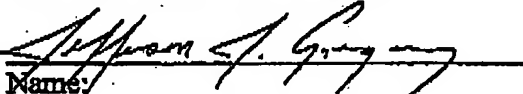
By Ortho-McNeil Pharmaceutical, Inc:

Name:

Title:

Date:

By King Pharmaceuticals, Inc.:



Name:

Title:

Date:

CONSENT OF JENCAP RESEARCH, Ltd and ROBERT F. CASPER

Jencap and Casper, for good and valuable consideration the sufficiency of which is hereby acknowledged, agree as follows:

- A) Jencap and Casper consent to this Agreement by OMP to KING of the rights and obligations described above.
- B) OMP agrees, in consideration of Jencap and Casper entering into this Agreement, to pay to Jencap the sum of [REDACTED] (the "Payment"). The Payment shall be made to Casper within five (5) business days after the Closing under the Asset Purchase Agreement. If the Asset Purchase Agreement does not close, then the Payment shall

- 15) This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement.
- 16) The article and section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.
- 17) This Agreement shall be construed, interpreted and the rights of the parties determined in accordance with the laws of the State of New Jersey without reference to the choice of law provisions thereof.
- 18) This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, OMP and KING have caused this agreement to be executed in duplicate by their duly authorized officer

By Onho-McNeil Pharmaceutical, Inc:

Patrick Verheyen
Name: PATRICK VERHEYEN

Title: V.P. Corp. Dev.

Date: April 26, 2002

By King Pharmaceuticals, Inc.:

Name:

Title:

Date:

CONSENT OF JENCAP RESEARCH, Ltd and ROBERT F. CASPER

Jencap and Casper, for good and valuable consideration the sufficiency of which is hereby acknowledged, agree as follows:

- A) Jencap and Casper consent to this Agreement by OMP to KING of the rights and obligations described above.
- B) OMP agrees, in consideration of Jencap and Casper entering into this Agreement, to pay to Jencap the sum of [REDACTED] (the "Payment"). The Payment shall be made to Casper within five (5) business days after the Closing under the Asset Purchase Agreement. If the Asset Purchase Agreement does not close, then the Payment shall

not be made (and this Agreement shall not become effective as specified in Section 2 above).


- C) Jencap and Casper from this date forward accept KING as solely accountable and responsible to fulfill the obligations previously owed by OMP and assigned to KING herein. Jencap and Robert F. Casper hereby release OMP from any further such obligations.
- D) Jencap and Casper acknowledge that any breach or default by KING or OMP of their respective obligations under this Agreement or the CASPER AGREEMENTS shall not be considered a breach or default by the other party under those same agreements.
- E) Jencap and Casper acknowledge that payment of a minimum royalty by OMP under Paragraph 4.1(c), of the License Agreement, which is referenced as CASPER AGREEMENTS (ii) in paragraph 1(a) hereinabove, shall meet OMP's payment obligations under Article IV of that License Agreement only with respect to the Product.
- F) Jencap and Casper represent and warrant that they have the unencumbered right to consent to this Agreement and to otherwise agree as set forth herein. Jencap and Casper further warrant that the CASPER AGREEMENTS are in full force and effect.
- G) Jencap and Casper, to their knowledge, represent and warrant that the CASPER PATENTS are valid and enforceable. Jencap and Casper, to their knowledge, further represent and warrant that all maintenance fees due and/or owed for the CASPER PATENTS have been timely paid. Jencap and Casper, to their knowledge, further represent and warrant that the CASPER PATENTS are not and have never been the subject of a Paragraph IV Certification, litigation or threatened litigation. Jencap and Casper, to their knowledge, further represent and warrant that the manufacture, use and/or sale of PRODUCT does not and has not infringed a claim in any United States Patent. Jencap and Casper, to their knowledge, further represent and warrant that they are unaware of any third party patent application, which is pending as of the Effective Date, that contains a claim, that if issued, would be infringed by the manufacture, use and/or sale of PRODUCT. Jencap represents and warrants that it owns all right, title and interest in, to and under U.S. Patent No. 5,108,995 and U.S. Patent No. 5,382,573, and co-owns all right, title and interest in, to and under U.S. Provisional Application No. 60/126,970, and that it has exclusively licensed the ~~Casper Patents to OMP only.~~ Casper represents and warrants that he has conveyed all right, title and interest in, to and under the Casper Patents to Jencap and that he had the right to do so.
- H) Jencap and Casper agree to appoint counsel designated by KING to prosecute and transact all business in the U.S. Patent and Trademark Office with respect to the CASPER PATENTS and KING agrees to accept responsibility to prosecute and transact all business in the U.S. Patent and Trademark Office with respect to the CASPER PATENTS. KING will not abandon the maintenance of the CASPER PATENTS without Casper and Jencap's consent, nor will KING fail to pay any

maintenance fees with respect to the CASPER PATENTS without Casper and Jencap's consent. Jencap and Casper further agree to revoke all existing powers granted to counsel currently designated to prosecute and transact all business in the U.S. Patent and Trademark Office with respect to the CASPER PATENTS. Jencap and Casper further agree to cooperate with and assist KING in connection with the prosecution and transaction of all business in the U.S. Patent and Trademark Office with respect to the OMP PATENTS. Jencap and Casper further hereby waive any and all conflicts that may arise out of, relate to or concern the prosecution and transaction of all business in the U.S. Patent and Trademark Office with respect to the CASPER PATENTS.

- I) Jencap and Casper further agree to file with the U.S. Patent and Trademark Office on or before May 1, 2002, a continuation of U.S. Patent Appln. No. 09/538,485 filed March 30, 2000.
- J) The foregoing warranties will expire 18 months following the Effective Date of this Agreement.

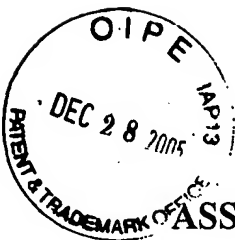
AGREED TO BY:

By Jencap Research, Ltd:


Name: ROBERT F. CASPER
Title: PRESIDENT
Date: APRIL 26, 2002

By Robert F. Casper:


Date: APRIL 26, 2002



ASSET PURCHASE AGREEMENT (PREFEST)

This Asset Purchase Agreement (Prefest) (this "Agreement") is made and entered into as of November 20, 2004, by and between Duramed Pharmaceuticals, Inc., a Delaware corporation ("Buyer") and King Pharmaceuticals, Inc., a Tennessee corporation ("Seller").

RECITALS

WHEREAS, Seller and certain of its Affiliates (as defined below) are engaged in the Business (as defined herein); and

WHEREAS, subject to the terms and conditions of this Agreement, Seller desires to sell to Buyer, and Buyer desires to purchase from Seller, certain of the assets, tangible and intangible, associated with the Business.

AGREEMENT

NOW, THEREFORE, in consideration of the premises and the mutual covenants and promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which hereby are acknowledged, the Parties agree as follows:

Article I. Definitions

Section 1.01 Defined Terms.

As used in this Agreement, the following defined terms have the meanings described below:

(a) "Accountants" means an accounting firm of national reputation (excluding Buyer's and Seller's respective accounting firms) as may be mutually acceptable to the Parties.

(b) "Accounts Receivable" means all trade accounts and notes receivable and other miscellaneous receivables of the Business, including those that are not evidenced by instruments or invoices, existing as of the Closing.

(c) "Action or Proceeding" means any cause of action, suit, proceeding, arbitration, Order, inquiry, hearing, assessment with respect to fines or penalties or litigation (whether civil, criminal, administrative, investigative or informal) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental or Regulatory Authority.

(d) "Adverse Effect" means an effect, condition or change that individually or in the aggregate is materially adverse to the Purchased Assets taken as a whole, other than changes in general economic or market conditions or changes or developments generally affecting the pharmaceutical industry.

(zzz) "Tax" means all of the following taxes (with the exception of income taxes attributable to the Seller or any of its Affiliates) in connection with the operations of the Business or the transactions contemplated hereby: (i) any net income, alternative or add-on minimum tax, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, excise, severance, stamp, occupation, premium, property, environmental or windfall profit tax, custom, duty or other tax, governmental fee or other like assessment imposed by an governmental, regulatory or administrative entity or agency responsible for the imposition of any such tax; (ii) any Liability for the payment of any amounts of the type described in clause (i) above as a result of being a member of any affiliated, consolidated, combined, unitary or other group for any Taxable period; and (iii) any Liability for the payment of any amounts of the type described in clause (i) or (ii) above as a result of any express or implied obligation to indemnify any other person.

(aaaa) "Third Party Claim" has the meaning set forth in Section 11.02(d).

(bbbb) "WAC" has the meaning set forth in Section 8.11(f).

Section 1.02 Construction of Certain Terms and Phrases.

Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms "hereof," "herein," "hereby" and derivative or similar words refer to this entire Agreement; (d) the terms "Article", "Section" or "Exhibit" refer to the specified Article, Section or Exhibit of this Agreement; (e) the term "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase "and/or"; (f) "Dollars" or "\$" means United States dollars; and (g) the terms "including" and "includes" mean "including without limitation" and "includes without limitation," respectively. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified.

Article II. Purchase and Sale of Assets

Section 2.01 Purchase and Sale of Assets.

(a) Subject to the terms and conditions of this Agreement, at the Closing, Seller shall, or shall cause its relevant Affiliates to, sell, assign, transfer, convey and deliver to Buyer, and Buyer shall purchase, acquire and accept from Seller and such Affiliates of Seller, all of Seller's and each such Affiliate's right, title and interest, as of the Closing, in and to the Purchased Assets.

(b) Buyer acknowledges and agrees that the Purchased Assets do not include, and Seller and its Affiliates are not selling or conveying to Buyer, any rights in or to any intellectual property except for the Product Intellectual Property, the Casper Rights, the Dedicated Business Know-How, and the Licensed Business Know-How.

(c) Notwithstanding anything contained in this Agreement to the contrary, (i) from and after the Closing, Seller and its Affiliates shall retain all of their right, title

its Affiliates or such third party contractors were not in compliance with applicable Law with respect to the Product in the United States except, with respect to this subsection (ii), warning letters and other written correspondence that could not reasonably be expected to have an Adverse Effect. During the two (2) years prior to the date of this Agreement, there has not been any occurrence of any product recall, market withdrawal or replacement, or post-sale warning conducted by or on behalf of Seller concerning the Product in the United States or any product recall, market withdrawal or replacement conducted by or on behalf of any entity as a result of any alleged defect in the Product in the United States, and Seller has made available to Buyer every complaint and notice of alleged defect or adverse reaction with respect to the Product in the United States that has been received in writing by Seller and its Affiliates or that has been orally transmitted to and recorded by Seller and its Affiliates.

Section 6.09 Brokers.

[REDACTED]

Section 6.10 Product Intellectual Property.

(a) All necessary registration, maintenance and renewal fees due in connection with the Registered Intellectual Property have been paid and all necessary documents and certificates in connection with such Registered Intellectual Property have been filed with the relevant patent, trademark or other Governmental or Regulatory Authorities for the purposes of maintaining such Registered Intellectual Property.

(b) Neither Seller nor any of its Affiliates has received any written notice from any Person, or has Knowledge, that the use of the Product Intellectual Property in connection with the Purchased Assets, infringes the intellectual property rights of any Person.

(c) Neither Seller nor any of its Affiliates has received any written notice from any Person, or has Knowledge, of any unauthorized use, infringement or misappropriation of any of the Product Intellectual Property by any Person.

(d) Except as set forth in Section 6.10(d) of the Seller Disclosure Schedule, to the Knowledge of Seller, all of the patents listed on Section 1.01(ppp) of the Seller Disclosure Schedule are valid, subsisting and enforceable. None of the patents listed on Section 1.01(ppp) of the Seller Disclosure Schedule are currently involved in any interference, reissue, reexamination or opposition proceeding, and neither the Seller nor any of its Affiliates has received any written notice from any Person, or has Knowledge, of any claim or assertion to the contrary.

(e) Except as set forth in Section 6.10(e) of the Seller Disclosure Schedule, to the Knowledge of the Seller, there are no Actions or Proceedings (including any inventorship challenges) pending with respect to any of the Registered Intellectual Property, nor have any such Actions or Proceedings been brought during the past two (2) years.

(f) To the Knowledge of Seller, none of the Product Trademarks listed in Section 1.01(ppp) of the Seller Disclosure Schedule is or has been the subject of any invalidation, opposition, cancellation, abandonment or similar proceeding, and neither the Seller nor any of its Affiliates has received any written notice from any Person, or has Knowledge, of any actual or threatened claim or assertion to the contrary. To the Knowledge of Seller, there are no trademarks or trademark registrations or applications of any Person that are interfering or potentially interfering with the Product Trademarks listed in Section 1.01(ppp) of the Seller Disclosure Schedule.

(g) Section 6.10(g) of the Seller Disclosure Schedule sets forth a complete and accurate list of each Contract pursuant to which the Seller or its Affiliates have license or other similar rights to patents or trademarks used by them in the Business as conducted on the date hereof.

(h) To the Knowledge of Seller, (i) Seller does not possess any Know-How material to the manufacture or preparation of the Product; and (ii) the use of the Licensed Business Know-How and the Dedicated Business Know-How as of the date hereof in connection with the Purchased Assets does not infringe the intellectual property rights of any Person.

(i) The Product Intellectual Property, the Casper Rights, the Dedicated Business Know-How, the Licensed Business Know-How and the Manufacturing Patent constitute all of the intellectual property owned, used or held for use by Seller or its Affiliates in connection with the manufacturing or preparation of the Product as conducted on the date hereof.

Section 6.11 Title.

(a) Except as set forth in Section 6.11(a) of the Seller Disclosure Schedule, (i) Seller or one of its Affiliates has good and marketable title to the Purchased Assets, free and clear of all Encumbrances, other than Permitted Encumbrances, (ii) to Seller's Knowledge, there are no adverse claims of ownership to the Purchased Assets; and (iii) neither Seller nor any of its Affiliates has received written notice that any Person or Persons has asserted a claim of ownership or right of possession or use in and to any of the Purchased Assets.

(b) Except as set forth in Section 6.11(b) of the Seller Disclosure Schedule, at Closing, Seller and its Affiliates will transfer to Buyer good and marketable title to the Purchased Assets, free and clear of all Encumbrances, other than Permitted Encumbrances.

Section 6.12 Financial Information/Books and Records.

[REDACTED]

(b) The Books and Records are true and accurate copies of the original files, documents, papers, instruments, books and records they purport to duplicate.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties as of
the date first above written.

KING PHARMACEUTICALS, INC.

By: 

Name: Brian A. Markison

Title: President & Chief Executive Officer

DURAMED PHARMACEUTICALS, INC.

By: _____

Name:


Title:

IN WITNESS WHEREOF, this Agreement has been executed by the Parties as of
the date first above written.

KING PHARMACEUTICALS, INC.

By: _____
Name:
Title:

DURAMED PHARMACEUTICALS, INC.

By: 
Name: *Paul Bisaro*
Title: *President*



Section 1.01(ppp)

Registered Intellectual Property

Product Trademark Registrations

1. Prefest®, U.S. Reg. No. 2,744,696

Patents

1. U.S. Patent 6,747,019*
2. U.S. Application No. 10/806,613*

Internet Domain Names

1. .prefest.com
2. .prefest.org
3. .prefesthrt.com

* Co-owned. See Schedules 6.11(a) and 6.11(b).

Section 6.11(a)

Title of Seller to Purchased Assets

1. On November 2, 2004, Johnson & Johnson, the owner of Reg. No. 2,390,387 for the mark ORTHO-PREFEST, filed a Notice of Surrender of Registration for such trademark.
2. Seller co-owns U.S. Patent 6,747,019 and U.S. Application No. 10,806,613 with Jencap Research, Ltd. and Robert F. Casper. Seller submitted a copy of the Assignment of Rights and Obligations, entered into as of April 26, 2002, by and between Ortho-McNeil Pharmaceutical, Inc. and Seller and agreed to by Jencap Research, Ltd. and Robert F. Casper to the United States Patent and Trademark Office to evidence such co-ownership on October 29, 2004.

Section 6.11(b)

Exceptions to Good and Marketable Title of Buyer in Purchased Assets

1. After the transfer of the Purchased Assets from the Seller to the Buyer, Buyer will co-own U.S. Patent 6,747,019 and U.S. Application No. 10,806,613 with Jencap Research, Ltd. and Robert F. Casper.

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